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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,714	03/05/2002	Isabelle Mansuy	64481/JPW/AJM/MML	7463

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EXAMINER	
FALK, ANNE MARIE	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,714	MANSUY ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-34 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a transgenic nonhuman mammal comprising a transgene as recited in the claims, wherein the transgene is present in germline cells and somatic cells (e.g., an animal generated by transgenesis), classified in class 800, subclass 13.

II. Claims 1-10, drawn to a transgenic nonhuman mammal comprising the transgene as recited in the claims, wherein the transgene is present in somatic cells, but is not present in germline cells (e.g., an animal generated by *in vivo* somatic cell genetic modification or by transplantation of genetically modified cells), classified in class 800, subclass 8.

III. Claims 11-20, drawn to a mammalian cell comprising a transgene as recited in the claims, classified in class 435, subclass 325.

IV. No claims, drawn to a nucleic acid molecule or a pair of nucleic acid molecules as recited in Claim 21, or an acellular solution comprising the nucleic acid molecules, classified in class 435, subclass 320.1.

V. Claim 31, 33, and 34, drawn to a method for determining whether an agent inhibits long-term potentiation in a mammal, classified in class 800, subclass 3.

VI. Claim 32, drawn to a method for determining whether an agent inhibits long-term potentiation in a cell, classified in class 435, subclass 4.

Claims 1-10 embrace the inventions of Groups I and II. Should either of Groups I or II be elected, Claims 1-10 will be examined only to the extent that they encompass the elected subject matter.

Claims 21-30 link the inventions of Groups I-IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 21-30.

Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the inventions are drawn to distinct compositions that are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the transgenic animal of the invention of Group I is not disclosed as being used together with the transgenic animal of the invention of Group II. The animals are structurally, chemically, biologically, and functionally distinct from each other. Furthermore, an animal that has a particular transgene present throughout the entire animal body (Group I) would be expected to differ phenotypically from an animal that has the transgene present only within a particular subpopulation of cells within the animal body (Group II). Thus, the animal of the invention of Group I would have a different use from the animal of the invention of Group II, based on its different

phenotype. Thus, the animal of the invention of Group I is patentably distinct from the animal of the invention of Group II.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the subcombination, i.e. the mammalian cell of the invention of Group III, has separate utility such as use in assays carried out in cell culture or to recombinantly produce the encoded protein in culture. Thus, the animal of the invention of Group I is patentably distinct from the cells of the invention of Group III.

Inventions I and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the subcombination, i.e. the nucleic acid molecule of the invention of Group IV, has separate utility such as for use in transfecting cells *in vitro* for the purpose of producing the encoded protein in culture. Thus, the animal of the invention of Group I is patentably distinct from the nucleic acid molecule of the invention of Group IV.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed, i.e. the transgenic mammal of the invention of Group I, can be used to harvest cells for *in vitro* assays, thus demonstrating a materially different process of using that product and meeting criteria (2). Thus, the animal of the invention of Group I is patentably distinct from the method of the invention of Group V.

Inventions I and VI are patentably distinct because the inventions are unrelated. Inventions are ed if it can be shown that they are not disclosed as capable of use together and they have different of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the case, the animal of the invention of Group I is not required for and cannot be used in the method of ention of Group VI. Thus, the inventions are not disclosed as capable of use together. Thus, the of the invention of Group I is patentably distinct from the method of the invention of Group IV.

Inventions II and III are related as combination and subcombination. Inventions in this ship are distinct if it can be shown that (1) the combination as claimed does not require the lars of the subcombination as claimed for patentability, and (2) that the subcombination has utility f or in other combinations (MPEP § 806.05(c)). In the instant case, the subcombination, i.e. the alian cell of the invention of Group III, has separate utility such as for use in assays carried out in ture or to recombinantly produce the encoded protein in culture. Thus, the animal of the invention up II is patentably distinct from the cells of the invention of Group III.

Inventions II and IV are related as combination and subcombination. Inventions in this ship are distinct if it can be shown that (1) the combination as claimed does not require the ars of the subcombination as claimed for patentability, and (2) that the subcombination has utility f or in other combinations (MPEP § 806.05(c)). In the instant case, the subcombination, i.e. the acid molecule of the invention of Group IV, has separate utility such as for use in transfecting *vitro* for the purpose of producing the encoded protein in culture. Thus, the animal of the on of Group II is patentably distinct from the nucleic acid molecule of the invention of Group IV.

Inventions II and V are related as product and process of use. The inventions can be shown to be if either or both of the following can be shown: (1) the process for using the product as claimed practiced with another materially different product or (2) the product as claimed can be used in a

materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed, i.e. the transgenic mammal of the invention of Group II, can be used to harvest cells for *in vitro* assays, thus demonstrating a materially different process of using that product and meeting criteria (2). Thus, the animal of the invention of Group II is patentably distinct from the method of the invention of Group V.

Inventions II and VI are patentably distinct because the inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the animal of the invention of Group II is not required for and cannot be used in the method of the invention of Group VI. Thus, the inventions are not disclosed as capable of use together. Thus, the animal of the invention of Group II is patentably distinct from the method of the invention of Group IV.

Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the subcombination, i.e. the nucleic acid molecule of the invention of Group IV, has separate utility such as for *in vivo* administration to an adult animal to effect *in vivo* expression of the encoded heterologous protein. Thus, the mammalian cell of the invention of Group III is patentably distinct from the nucleic acid molecule of the invention of Group IV.

Inventions III and V are patentably distinct because the inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the mammalian cell of the invention of Group III is not required for and cannot be used in

the method of the invention of Group V. Thus, the inventions are not disclosed as capable of use together. Thus, the mammalian cell of the invention of Group III is patentably distinct from the method of the invention of Group V.

Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed, i.e. the mammalian cell of the invention of Group III, can be used to produce the encoded protein in culture, thus demonstrating a materially different process of using that product and meeting criteria (2). Thus, the mammalian cell of the invention of Group III is patentably distinct from the method of the invention of Group VI.

Inventions IV and V are patentably distinct because the inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acid molecule of the invention of Group IV is not required for and cannot be used in the method of the invention of Group V, which requires a transgenic animal. Thus, the inventions are not disclosed as capable of use together. Thus, the nucleic acid molecule of the invention of Group IV is patentably distinct from the method of the invention of Group V.

Inventions IV and VI are patentably distinct because the inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acid molecule of the invention of Group IV is not required for and cannot be used in the method of the invention of Group V, which requires a mammalian hippocampal tissue sample.

Thus, the inventions are not disclosed as capable of use together. Thus, the nucleic acid molecule of the invention of Group IV is patentably distinct from the method of the invention of Group VI.

Inventions V and VI are patentably distinct because the inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the two methods use different starting materials, require different method steps, have different modes of operation, and produce different results, thus demonstrating that they are not disclosed as capable of being used together. Thus, the method of the invention of Group V is patentably distinct from the method of the invention of Group VI.

Each of the inventions of Groups I-VI requires consideration of separate issues relating to assessment of novelty, obviousness, utility, written description, and enablement. For example, the invention of Group I requires consideration of issues relating to the utility of a transgenic animal which is not required for examination of the invention of Group III or IV. Furthermore, the searches for the inventions of Groups I-VI are not coextensive. For example, a search for the transgenic mammal of the invention of Group I would not necessarily identify art teaching the transgenic animal of the invention of Group II, which is structurally distinct because the transgene resides only in a subpopulation of cells within the animal. Additional searching would be required to cover the transgenic animal of the invention of Group II. Thus, search and examination of all 6 inventions in a single patent application constitutes a serious burden on the Office.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and

because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER